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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,782	04/02/2004	Steven Griffiths	VA/H-32318B	3493

1095 7590 01/24/2006

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,782	GRIFFITHS ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/049,086.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Alignment*.

DETAILED ACTION

1. Applicant's preliminary amendment filed December 12, 2003 is acknowledged and entered. Claims 38-42 are pending and under examination.

Amendment to Correct Inventorship 37 C.F.R. 1.48(a)

2. In view of the papers filed January 18, 2005, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding the name Joel Heppell as one of the co-inventors.

Specification

3. The specification is objected to because of the following:

- The sequences in the drawings must be referenced by sequence identifiers. (SEQ ID NO:)
- The first line of the first page of the specification fails to reflect the updated status of parent application USSN 10/049,086, now US Patent 6,919,083.
- Figures 7 and 8 are not referenced in the specification.

Correction is required to overcome these objections to the specification.

Priority

4. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Certified copies of 9918588.6 and 0005848.7 have been filed in parent

Application No. 10/049,086, filed on February 6, 2002. It is noted, however, that Applicant has not filed a certified copy of the 0006674.6 application as required by 35 U.S.C. 119(b). The examiner notes that this document has been previously indicated as present in the parent application. However, a copy of the document cannot be located in the parent application. Applicant is requested to file a copy of the document. The Office regrets any inconvenience.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to an isolated protein comprising an amino acid sequence according to SEQ ID NO: 4 or a derivative thereof, wherein the derivative thereof has antigenic or immunogenic characteristics of the amino acid sequence according to SEQ ID NO: 4. Also claimed are kits, vaccines and pharmaceutical compositions comprising the claimed peptide.

The metes and bounds of the claimed peptide derivative cannot be determined without a clear definition of the derivative. While Applicant has provided a functional definition of the claimed peptide, the structural definition is lacking. It is unclear what portions of SEQ ID NO: 4 are retained in the derivative so that it remains immunogenic. Further, it is unclear what antigenic or immunogenic characteristics of the derived peptide must be shared with SEQ ID NO: 4. It is suggested that references to derivatives be deleted from the claims in order to overcome this rejection.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. With regard to SEQ ID NO: 4, US Patent 6,471,964 B1, discloses and claims a sequence having 97.4% sequence identity to SEQ ID NO: 4 (see attached Sequence Alignment). Because the priority date granted to the patent (October 18, 1999) is later than the earliest priority date of the instant application (August 8, 1999), the patent is not available as prior art, although the derivatives instantly claimed are encompassed by the disclosure and claims of the patent.

No claim is allowed. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
January 18, 2006

—Sequence Alignment—

GenCore version 5.1.6

OM protein - protein search, using sw model

Run on: January 13, 2006, 09:27:05 ; Search time 27 Seconds
(without alignments)
1886.230 Million cell updates/sec

Title: US-10-734-782-4
Perfect score: 3097
Sequence: 1 MADKGMTYSFDVRDNTLVVR.....DMTPEIEFDEDDEEEEDIDI 616

Scoring table: BLOSUM62
Gapop 10.0 , Gapext 0.5

Searched: 572060 seqs, 82675679 residues

Total number of hits satisfying chosen parameters: 572060

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

Database : Issued_Patents_AA:*
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6: /cgn2_6/ptodata/1/iaa/backfiles1.pep:*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	% Query Match	Length	DB	ID	Description
1	3097	100.0	616	2	US-10-049-086-4	Sequence 4, Appli
2	3015	97.4	616	2	US-09-690-185A-2	Sequence 2, Appli
3	128	4.1	1095	2	US-09-206-942-45	Sequence 45, Appl
4	128	4.1	1101	2	US-09-206-942-43	Sequence 43, Appl
5	118	3.8	564	2	US-09-107-532A-6970	Sequence 6970, Ap
6	116.5	3.8	2042	2	US-09-077-098A-6	Sequence 6, Appli
7	116.5	3.8	2042	2	US-10-192-584-6	Sequence 6, Appli
8	116	3.7	1166	2	US-09-200-650E-7	Sequence 7, Appli
9	116	3.7	1781	1	US-08-477-451-11	Sequence 11, Appl
10	115	3.7	1095	2	US-09-206-942-69	Sequence 69, Appl
11	115	3.7	1095	2	US-10-193-764-65	Sequence 65, Appl
12	115	3.7	1536	1	US-08-038-682-2	Sequence 2, Appli
13	115	3.7	1536	1	US-08-302-832-2	Sequence 2, Appli
14	115	3.7	1536	1	US-08-530-198-2	Sequence 2, Appli
15	115	3.7	1536	1	US-08-469-880-2	Sequence 2, Appli
16	115	3.7	1536	1	US-08-728-470-2	Sequence 2, Appli
17	115	3.7	1536	1	US-08-617-697-2	Sequence 2, Appli
18	115	3.7	1536	2	US-08-719-641-2	Sequence 2, Appli
19	115	3.7	1536	2	US-09-206-942-67	Sequence 67, Appl
20	115	3.7	1536	2	US-10-193-764-63	Sequence 63, Appl
21	114	3.7	2048	2	US-09-268-347-48	Sequence 48, Appl
22	114	3.7	3241	2	US-09-841-786-1	Sequence 1, Appli
23	113	3.6	504	2	US-09-949-016-7935	Sequence 7935, Ap
24	112.5	3.6	1572	2	US-09-710-279-2906	Sequence 2906, Ap
25	112.5	3.6	4536	2	US-09-180-422B-27	Sequence 27, Appl
26	112.5	3.6	4536	2	US-09-079-030-1	Sequence 1, Appli
27	112.5	3.6	4563	2	US-09-108-006C-1	Sequence 1, Appli
28	112.5	3.6	4563	2	US-09-538-092-842	Sequence 842, App
29	111.5	3.6	1312	2	US-09-345-882-29	Sequence 29, Appl
30	111.5	3.6	1312	2	US-10-071-179-29	Sequence 29, Appl
31	111	3.6	789	2	US-09-134-000C-4939	Sequence 4939, Ap
32	111	3.6	1833	2	US-08-621-944A-4	Sequence 4, Appli
33	111	3.6	1833	2	US-08-945-567D-4	Sequence 4, Appli
34	111	3.6	1992	2	US-08-621-944A-3	Sequence 3, Appli
35	111	3.6	1992	2	US-08-945-567D-3	Sequence 3, Appli
36	110.5	3.6	1129	2	US-09-252-991A-29927	Sequence 29927, A
37	110	3.6	2123	2	US-08-968-685A-10	Sequence 10, Appl
38	109.5	3.5	1477	1	US-08-038-682-4	Sequence 4, Appli
39	109.5	3.5	1477	1	US-08-302-832-4	Sequence 4, Appli
40	109.5	3.5	1477	1	US-08-530-198-4	Sequence 4, Appli
41	109.5	3.5	1477	1	US-08-469-880-4	Sequence 4, Appli
42	109.5	3.5	1477	1	US-08-728-470-4	Sequence 4, Appli
43	109.5	3.5	1477	1	US-08-617-697-4	Sequence 4, Appli
44	109.5	3.5	1477	2	US-08-719-641-4	Sequence 4, Appli
45	109	3.5	1004	2	US-09-206-942-57	Sequence 57, Appl

ALIGNMENTS

RESULT 1
US-10-049-086-4
; Sequence 4, Application US/10049086
; Patent No. 6919083
; GENERAL INFORMATION:
; APPLICANT: Aqua Health (Europe) Limited
; APPLICANT: Griffiths, Steven
; APPLICANT: Ritchie, Rachael
; TITLE OF INVENTION: Sequence
; FILE REFERENCE: P24268-/GST/RMC
; CURRENT APPLICATION NUMBER: US/10/049,086
; CURRENT FILING DATE: 2002-02-06
; PRIOR APPLICATION NUMBER: GB9918588.6
; PRIOR FILING DATE: 1999-07-08
; PRIOR APPLICATION NUMBER: GB0005848.7
; PRIOR FILING DATE: 2000-03-11
; PRIOR APPLICATION NUMBER: GB0006674.6
; PRIOR FILING DATE: 2000-03-21
; NUMBER OF SEQ ID NOS: 10
; SOFTWARE: PatentIn version 3.0
; SEQ ID NO 4
; LENGTH: 616
; TYPE: PRT
; ORGANISM: Salmon Anaemia Virus
US-10-049-086-4

Query Match 100.0%; Score 3097; DB 2; Length 616;
Best Local Similarity 100.0%; Pred. No. 3.7e-309;
Matches 616; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy          1 MADKGMTYSFDVRDNTLVVRRSTATKSGIKISYREDRGTSLLQKAFAGTEDEFWVELDQD 60
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Db          1 MADKGMTYSFDVRDNTLVVRRSTATKSGIKISYREDRGTSLLQKAFAGTEDEFWVELDQD 60

Qy         61 VYVDKKIRKPLEEEKMKDMSTRVSGAVAAAIERSVEFDNFSKEAAANIEMAGVDDEEAGG 120
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Db         61 VYVDKKIRKPLEEEKMKDMSTRVSGAVAAAIERSVEFDNFSKEAAANIEMAGVDDEEAGG 120

Qy        121 SGLVDNRRKNKGVSNMAYNLSLFIGMVFPALTTFFSAILSEGEMSIWQNGQAIIRILALA 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 SGLVDNRRKNKGVSNMAYNLSLFIGMVFPALTTFFSAILSEGEMSIWQNGQAIIRILALA 180

Qy        181 DEDGKRQTRTGGQRVDMADVTKLNVVTANGKVKQVEVNLNDLKAAFRQSRPKRSDYRKGQ 240
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Qy        361 FQRIMDTLCTSFLIDPPRTTKCFIPPISSLMMYIQEGNSVLAMDFMKNGEDACKICREAK 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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RESULT 2
US-09-690-185A-2
; Sequence 2, Application US/09690185A
; Patent No. 6471964
; GENERAL INFORMATION:
; APPLICANT: BIERING, EIRIK
; APPLICANT: KROSSOY, BJORN
; TITLE OF INVENTION: DNA ENCODING STRUCTURAL PROTEIN-1 OF INFECTIOUS SALMON
; TITLE OF INVENTION: ANAEMIA VIRUS AND USES THEREOF
; FILE REFERENCE: BIERING
; CURRENT APPLICATION NUMBER: US/09/690,185A
; CURRENT FILING DATE: 2000-10-17
; PRIOR APPLICATION NUMBER: EP99203401.7
; PRIOR FILING DATE: 1999-10-18
; NUMBER OF SEQ ID NOS: 8
; SOFTWARE: PatentIn Ver. 2.1
; SEQ ID NO 2
; LENGTH: 616
; TYPE: PRT
; ORGANISM: Infectious salmon anemia virus
US-09-690-185A-2

Query Match 97.4%; Score 3015; DB 2; Length 616;
Best Local Similarity 96.3%; Pred. No. 1e-300;
Matches 593; Conservative 17; Mismatches 6; Indels 0; Gaps 0;

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Qy         61 VYVDKKIRKFLEEEKMKDMSTRVSGAVAAAIERSVEFDNFSKEAAANIEMAGVDDEEAGG 120
              |||||:|||||||||||||| | ||:||||||||||||||||||||:| |:|||||
Db         61 VYVDKRIRKFLEEEKMKDMSPRCSGSVAAAIERSVEFDNFSKEAAANIEMSGEDEEEAGG 120

Qy        121 SGLVDNRRKNKGVSNMAYNLSLFIGMVFPALTTFFSAILSEGEMSIWQNGQAIIRILALA 180
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              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy        361 FQRIMDTLCTSFLIDPPRTTKCFIPPISSLMMYIQEGNSVLAMDFMKNGEDACKICREAK 420
              ||||||||||||||||||||||||||||||||||||||||:|||:|||||||||||:||||||
Db        361 FQRIMDTLCTSFLIDPPRTTKCFIPPISSLLTYIQDGNSVLAMDFMKNGEDACRICREAK 420

Qy        421 LKVGVNSTFTMSVARTCVAVSMVATAFCSADIIENAVPGSERYRSNIKANTTKPKKDSTY 480
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Qy        601 EIEFDEDDEEEEDIDI 616
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Db        601 DIEFDEDDQEEEDTDI 616
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RESULT 3
US-09-206-942-45
; Sequence 45, Application US/09206942
; Patent No. 6432669
; GENERAL INFORMATION:
; APPLICANT: Loosmore, Sheena M.
; APPLICANT: Yang, Yan-Ping
; APPLICANT: Klein, Michel H.
; TITLE OF INVENTION: Protective Recombinant Haemophilus Influenzae High
; TITLE OF INVENTION: Molecular Weight Proteins
; FILE REFERENCE: 1038-861 MIS:jb
; CURRENT APPLICATION NUMBER: US/09/206,942
; CURRENT FILING DATE: 1998-12-08
; EARLIER APPLICATION NUMBER: 09/167,568
; EARLIER FILING DATE: 1998-10-07
; NUMBER OF SEQ ID NOS: 95
; SOFTWARE: PatentIn Ver. 2.1
; SEQ ID NO 45
; LENGTH: 1095
; TYPE: PRT
; ORGANISM: Haemophilus influenzae
US-09-206-942-45

Query Match 4.1%; Score 128; DB 2; Length 1095;
Best Local Similarity 19.1%; Pred. No. 0.0023;
Matches 121; Conservative 73; Mismatches 264; Indels 176; Gaps 23;

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Db        332 NFNASEGSSLRFKSEGSTRTAFTIESDLTLNATGGNISLNQVAGIDGNLQKSLVAN--KN 389

Qy         79 MSTRVSGAVAAAIERSVEF-DNFSKEAAANIEMA----GVDDEEAGGSGLVDNRRKNKGV 133
              ::          ||:: :|   | : :  ||: :     | |         | | | : |  |
Db        390 ITFEGGNITLAADKKPIEIKGNITVKEGANVTLRSANYGNDKSALSIRGNVTN-KGNLTV 448

Qy        134 SNMAYNLSLFIGMVFPALTTFFSAILSEGEMSIWQNGQAIIRILALADEDGKRQ---TRT 190
              :  | |:                :  ||     |       :  | |  ||      :
Db        449 TGSAINIE-------------KNLTVEGSAKFLANPNYSFNVSGLFDNQGKSNISIAKG 494

Qy        191 GGQRVDMADVTKLNVVT---------------ANGKVK----------QVEVNLNDLKA 224
              |    |: :   ||: |              :|| :           |:  |::  :
Db        495 GAHFKDINNTKSLNITTNSDSAYRTIIEGNITNSNGDLNITDNKNNABIQIGGNISQKEG 554

Qy        225 AFRQSRPK-----RSDYRKGQGSKATESSISNQCMALIMKSVLSADQLFAPGVKMMRTNG 279
              |  |     :   :||   : ::|| :|      |     |   ||      :  :|
Db        555 NLTISSDKINITNQITIKKGVNKEDSDSSTANNANLTIKTKEL---QLTGD----LNISG 607

Qy        280 FNASYTTLAEGANIPSKYLRHMRNCGGVALDLMGMKRIKNSPEGAKSKIFSIIQKKVRGR 339
              |: :  |  |||::              ::|    |:    |     :  |:
Db        608 FDKAEITAKEGADL----------------IIGNSDNNNNANAKKVTFNQVKDSKISA- 649
```